

In re Application of: Andy Wolff et al  
Serial No.: 10/668,274  
Filed: September 24, 2006  
Office Action Mailing Date: December 29, 2006

Examiner: Elizabeth Macneill  
Group Art Unit: 3767  
Attorney Docket: 26486

**In the Claims:**

1. (currently amended) An oral device for controlled drug release, comprising:

a reservoir containing a drug;

an electronic drug release mechanism, for providing said controlled drug release; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard.

2. (original) The device of claim 1, wherein said electronic drug release mechanism further includes:

a control unit, for controlling said controlled release;

an electro-mechanical release mechanism, which opens to allow the release of said drug, responsive to commands from said control unit; and

a power source, for powering said control unit and electromechanical release mechanism.

3. (original) The device of claim 2, wherein said control unit is selected from the group consisting of a dedicated electronic circuitry, a processor, an ASIC, and a microcomputer.

4. (original) The device of claim 1, wherein said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof.

5. (original) The device of claim 1, and further including at least one local sensor, integrated with said device.

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6. (original) The device of claim 5, and further including at least two local sensors, integrated with said device.

7. (original) The device of claim 5, wherein said at least one local sensor is a physiological sensor, for drug release responsive to measurements of said sensor.

8. (original) The device of claim 7, wherein said local physiological sensor is selected from the group consisting of a sensor for drug concentration in the saliva, a sensor for glucose concentration in the saliva, a sensor for a metabolite concentration in the saliva, a sensor for an electrolyte concentration in the saliva, a sensor for the pH level in the saliva, a sensor for the temperature in the oral cavity, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

9. (original) The device of claim 5, wherein said at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition.

10. (original) The device of claim 9, wherein said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection.

11. (original) The device of claim 1, and further including at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver.

12. (original) The device of claim 11, wherein said communication component provides communication with a personal extracorporeal system.

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13. (original) The device of claim 12, wherein said personal extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination thereof.

14. (original) The device of claim 13, wherein said personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

15. (original) The device of claim 11, wherein said communication component provides communication with at least one remote sensor.

16. (original) The device of claim 15, wherein said remote sensor is selected from the group consisting of a sensor for drug concentration in the blood, a sensor for glucose concentration in the blood, a sensor for a metabolite concentration in the blood, a sensor for an electrolyte concentration in the blood, a sensor for oxygen level in the blood, a sensor for the pH level in the blood, a sensor for drug concentration in the interstitial fluid, a sensor for glucose concentration in the interstitial fluid, a sensor for a metabolite concentration in the interstitial fluid, a sensor for an electrolyte concentration in the interstitial fluid, a sensor for oxygen level in the interstitial fluid, a sensor for the pH level in the interstitial fluid, a sensor for drug concentration in the sweat, a temperature sensor, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

17. (original) The device of claim 1, wherein said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation, sonophoresis, and ablation.

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18. (original) The device of claim 1, wherein said drug release mechanism provides said controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate, delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system.

19. (canceled)

20. (original) The device of claim 1, wherein said drug is in nano-size particles.

21-24. (canceled)

25. (original) The device of claim 1, wherein said device is adapted to be removably inserted to the oral cavity of the subject.

26. (previously presented) The device of claim 1, wherein said device is adapted to be permanently inserted to the oral cavity of the subject.

27. (currently amended) The device of claim 221, wherein said device is adapted to be permanently inserted in the oral cavity of the subject, and said device further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure.

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28. (currently amended) A method of controlled drug release, comprising:

providing an oral device for controlled drug release, which comprises:

a reservoir containing a drug;

an electronic drug release mechanism, for providing said controlled drug release; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard; and

inserting said oral device to the oral cavity of a subject.

29. (original) The method of claim 28, wherein said electronic drug release mechanism further includes: a control unit, for controlling said controlled release; an electromechanical release mechanism, which opens to allow the release of said drug, responsive to commands from said control unit; and a power source, for powering said control unit and electromechanical release mechanism.

30. (original) The method of claim 29, wherein said control unit is selected from the group consisting of a dedicated electronic circuitry, a processor, an ASIC, and a microcomputer.

31. (original) The method of claim 28, wherein said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof.

32. (original) The method of claim 28, and further including at least one local sensor, integrated with said device.

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33. (original) The method of claim 32, and further including at least two local sensors, integrated with said device.

34. (original) The method of claim 32, wherein said at least one local sensor is a physiological sensor, for drug release responsive to measurements of said sensor.

35. (original) The method of claim 34, wherein said local physiological sensor is selected from the group consisting of a sensor for drug concentration in the saliva, a sensor for glucose concentration in the saliva, a sensor for a metabolite concentration in the saliva, a sensor for an electrolyte concentration in the saliva, a sensor for the pH level in the saliva, a sensor for the temperature in the oral cavity, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

36. (original) The method of claim 32, wherein said at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition.

37. (original) The method of claim 36, wherein said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection.

38. (original) The method of claim 28, and further including at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver.

39. (original) The method of claim 38, wherein said communication component provides communication with a personal extracorporeal system.

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40. (original) The method of claim 39, wherein said personal extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination thereof.

41. (original) The method of claim 40, wherein said personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

42. (original) The method of claim 38, wherein said communication component provides communication with at least one remote sensor.

43. (original) The method of claim 42, wherein said remote sensor is selected from the group consisting of a sensor for drug concentration in the blood, a sensor for glucose concentration in the blood, a sensor for a metabolite concentration in the blood, a sensor for an electrolyte concentration in the blood, a sensor for oxygen level in the blood, a sensor for the pH level in the blood, a sensor for drug concentration in the interstitial fluid, a sensor for glucose concentration in the interstitial fluid, a sensor for a metabolite concentration in the interstitial fluid, a sensor for an electrolyte concentration in the interstitial fluid, a sensor for oxygen level in the interstitial fluid, a sensor for the pH level in the interstitial fluid, a sensor for drug concentration in the sweat, temperature sensor, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

44. (original) The method of claim 28, wherein said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation, sonophoresis, and ablation.



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45. (original) The method of claim 28, wherein said drug release mechanism provides said controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate, delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system.

46. (canceled)

47. (original) The method of claim 28, wherein said drug is in nano-size particles.

48-51. (canceled)

52. (original): The method of claim 28, wherein said device is adapted to be removably inserted to the oral cavity of the subject.

53. (original): The method of claim 28, wherein said device is adapted to be permanently inserted to the oral cavity of the subject.

54. (currently amended): The method of claim 4928, wherein said device is adapted to be permanently inserted in the oral cavity of the subject, and said device further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure.



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55. (currently amended): An oral device for controlled drug release, comprising:

a reservoir containing a drug; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard.

~~a dental implement, for physically supporting said reservoir, said dental implement being designed to be inserted to the oral cavity of a subject.~~

56. (canceled)

57. (original): The device of claim 55, wherein said dental implement is designed to be removably inserted to the oral cavity of a subject.

58. (original): The device of claim 55, wherein said dental implement is designed to be permanently inserted to the oral cavity of a subject.

59. (previously presented): The device of claim 55, wherein said dental implement is designed to be permanently inserted in the oral cavity of the subject, and said dental implement further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure.

60. (canceled)

61. (original) The device of claim 55, wherein said drug reservoir contains a drug is a dosage form of nano-size particles.

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62. (original) The device of claim 55, and further including an electronic drug release mechanism.

63. (original) The device of claim 62, wherein said drug is in a controlled release dosage form for a combination of electronic and passive controlled release.

64. (canceled)

65. (original) The device of claim 55, wherein said electronic drug release mechanism further includes: a control unit, for controlling said controlled release; an electromechanical release mechanism, which opens to allow the release of said drug, responsive to commands from said control unit; and a power source, for powering said control unit and electromechanical release mechanism.

66. (original) The device of claim 65, wherein said control unit is selected from the group consisting of a dedicated electronic circuitry, a processor, an ASIC, and a microcomputer.

67. (original) The device of claim 55, wherein said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof.

68. (original) The device of claim 55, and further including at least one local sensor, integrated with said device.

69. (original) The device of claim 68, wherein said at least one local sensor is a physiological sensor, for drug release responsive to measurements of said sensor.

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70. (original) The device of claim 69, wherein said local physiological sensor is selected from the group consisting of a sensor for drug concentration in the saliva, a sensor for glucose concentration in the saliva, a sensor for a metabolite concentration in the saliva, a sensor for an electrolyte concentration in the saliva, a sensor for the pH level in the saliva, a sensor for the temperature in the oral cavity, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

71. (original) The device of claim 68, wherein said at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition.

72. (original) The device of claim 71, wherein said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection.

73. (original) The device of claim 55, and further including at least two local sensors, integrated with said device.

74. (original) The device of claim 55, and further including at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver.

75. (original) The device of claim 74, wherein said communication component provides communication with a personal extracorporeal system.

76. (original) The device of claim 75, wherein said local extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination

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thereof.

77. (original) The device of claim 76, wherein said personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

78. (original) The device of claim 74, wherein said communication component provides communication with at least one remote sensor.

79. (original) The device of claim 78, wherein said remote sensor is selected from the group consisting of a sensor for drug concentration in the blood, a sensor for glucose concentration in the blood, a sensor for a metabolite concentration in the blood, a sensor for an electrolyte concentration in the blood, a sensor for oxygen level in the blood, a sensor for the pH level in the blood, a sensor for drug concentration in the interstitial fluid, a sensor for glucose concentration in the interstitial fluid, a sensor for a metabolite concentration in the interstitial fluid, a sensor for an electrolyte concentration in the interstitial fluid, a sensor for oxygen level in the interstitial fluid, a sensor for the pH level in the interstitial fluid, a sensor for drug concentration in the sweat, a temperature sensor, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

80. (original) The device of claim 55, wherein said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation, sonophoresis, and ablation.

81. (original) The device of claim 55, wherein said drug release mechanism provides said controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate,

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delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system.

82. (original) The device of claim 55, wherein said drug is in nano-size particles.

83. (currently amended) A method of controlled drug release, comprising:

providing an oral device for controlled drug release, which comprises:

a reservoir containing a drug; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard,  
~~a dental implement, for physically supporting said reservoir, said dental implement being designed to be inserted to the oral cavity of a subject; and~~

inserting said oral device to the oral cavity of a subject.

84. (canceled)

85. (original) The method of claim 83, wherein said dental implement is designed to be removably inserted to the oral cavity of a subject.

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86. (original) The method of claim 83, wherein said dental implement is designed to be permanently inserted to the oral cavity of a subject.

87. (previously presented) The method of claim 83, wherein said dental implement is designed to be permanently inserted in the oral cavity of the subject, and said dental implement further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure.

88. (canceled)

89. (original) The method of claim 83, wherein said drug reservoir contains a drug is a dosage form of nano-size particles.

90. (original) The method of claim 83, and further including an electronic drug release mechanism.

91. (original) The method of claim 90, wherein said drug is in a controlled release dosage form for a combination of electronic and passive controlled release.

92. (canceled)

93. (original) The method of claim 83, wherein said electronic drug release mechanism further includes:

a control unit, for controlling said controlled release;

an electro-mechanical release mechanism, which opens to allow the release of said drug, responsive to commands from said control unit; and

a power source, for powering said control unit and electromechanical release mechanism.

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94. (original) The method of claim 93, wherein said control unit is selected from the group consisting of a dedicated electronic circuitry, a processor, an ASIC, and a microcomputer.

95. (original) The method of claim 83, wherein said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof.

96. (original) The method of claim 83, and further including at least one local sensor, integrated with said device.

97. (original) The method of claim 96, wherein said at least one local sensor is a physiological sensor, for drug release responsive to measurements of said sensor.

98. (original) The method of claim 97, wherein said local physiological sensor is selected from the group consisting of a sensor for drug concentration in the saliva, a sensor for glucose concentration in the saliva, a sensor for a metabolite concentration in the saliva, a sensor for an electrolyte concentration in the saliva, a sensor for the pH level in the saliva, a sensor for the temperature in the oral cavity, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

99. (original) The method of claim 96, wherein said at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition.

100. (original) The method of claim 99, wherein said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection.



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101. (original) The method of claim 83, and further including at least two local sensors, integrated with said device.

102. (original) The method of claim 83, and further including at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver.

103. (original) The method of claim 102, wherein said communication component provides communication with a personal extracorporeal system.

104. (original) The method of claim 103, wherein said local extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a laptop, and a combination thereof.

105. (original) The method of claim 104, wherein said personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

106. (original) The method of claim 102, wherein said communication component provides communication with at least one remote sensor.

107. (original) The method of claim 106, wherein said remote sensor is selected from the group consisting of a sensor for drug concentration in the blood, a sensor for glucose concentration in the blood, a sensor for a metabolite concentration in the blood, a sensor for an electrolyte concentration in the blood, a sensor for oxygen level in the blood, a sensor for the pH level in the blood, a sensor for drug concentration in the interstitial fluid, a sensor for glucose concentration in the interstitial fluid, a sensor for a metabolite concentration in the interstitial fluid, a

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sensor for an electrolyte concentration in the interstitial fluid, a sensor for oxygen level in the interstitial fluid, a sensor for the pH level in the interstitial fluid, a sensor for drug concentration in the sweat, a temperature sensor, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

108. (original) The method of claim 83, wherein said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation, sonophoresis, and ablation.

109. (original) The method of claim 83, wherein said drug release mechanism provides said controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate, delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system.

110. (original) The method of claim 83, wherein said drug is in nano-size particles.